

**UNITED STATES PATENT APPLICATION**

*of*

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*for a*

**METHOD AND APPARATUS FOR MEASURING INTRAVASCULAR BLOOD  
FLOW**

## METHOD AND APPARATUS FOR MEASURING INTRAVASCULAR BLOOD FLOW

[0001] This invention relates to the measurement of intravascular blood flow. It relates especially to a method and apparatus for measuring such flow utilizing microwave radiometry.

### BACKGROUND OF THE INVENTION

[0002] There are many instances when it is desirable or necessary to know the rate of flow of blood through a particular blood vessel of a patient for diagnostic purposes and in preparation for a surgical procedure. This flow rate may vary due to various factors such as the patient's blood pressure, presence of arthroscopic plaques which may partially occlude a blood vessel, etc.

[0003] The conventional method of measuring blood flow utilizes so-called thermodilution. An intravascular catheter carrying a temperature sensor such as a thermister or thermocouple is introduced into the pulmonary artery. Then saline is injected into the right atrium or ventricle to allow proper mixing of saline in the blood. Sometimes the saline is a room temperature but more often it is at a lower temperature, e.g. 4 C to increase the temperature difference from the patient's normal core temperature. The distance from the point of saline rejection to the sensor in the catheter is known more or less. Each time a saline bolus is injected, a clock is started to measure the time it takes for that

bolus to flow to the sensor which thereupon emits a signal to stop the clock. The flow rate is determined by the dividing that fixed distance by the measured time interval.

[0004] In some situations, it may not be desirable to inject saline solution into the patient's blood stream. This is particularly so for neonates whose blood volume is small. In addition, the distance between the point of saline injection and the sensor is not always known exactly. Those prior flow rate measuring devices which utilize temperature sensors such as thermistors and the like are also disadvantaged in that the sensors are not particularly sensitive and require recalibration because their thermal resistive characteristics may change over time.

## SUMMARY OF THE INVENTION

[0005] Accordingly, it is an object of the present invention to provide an improved method of measuring intravascular blood flow.

[0006] Another object of the invention is to provide such a method which avoids the use of conventional temperature sensors such as thermistors, thermocouples and the like.

[0007] Another object of the invention is to provide a flow rate measuring method which does not require the introduction of a foreign fluid into the patient's blood stream.

[0008] Another object of the invention is to provide microwave apparatus for measuring a patient's intravascular blood flow in accordance with the above method and which produces all of the above advantages.

[0009] Other objects will, in part, be obvious and will, in part, appear hereinafter.

**[0010]** The invention accordingly comprises the several steps at the relation of one or more of such steps with respect to each of the others, and the apparatus embodying the features of construction, combination of elements and arrangement of parts which are adapted to effect such steps, all is exemplified in the following detailed description and the scope of the invention will be indicated in the claims.

**[0011]** Briefly, the present method utilizes microwave radiometry to measure intravascular blood flow. In accordance with the method, an intravascular catheter containing first and second axially spaced apart antennas is introduced into a patient's blood vessel. The catheter is connected to an extracorporeal control unit which includes a microwave transmitter capable of delivering microwave energy pulses having a first frequency to the first antenna to heat a small volume of blood adjacent to that antenna. The control unit also includes a microwave receiver connected to the second antenna and which operates at a second frequency so that when the volume of blood heated by the first antenna passes the second antenna, that thermal anomaly is picked up by the second antenna which thereupon delivers a corresponding signal to the receiver. In addition, the control unit has a processor which controls the operation of the transmitter and receiver and can compute the time interval between each transmitter pulse and the corresponding signal picked up by the receiver and divide that time interval into the known distance between the two antennas to provide the flow rate of the blood in the patient's vessel, which rate may be displayed on a display device in the control unit.

**[0012]** Preferably, the first and second antennas in the catheter are coaxial with the second antenna, i.e. the receiving antenna, extending beyond the first or transmitting antenna. Preferably also, the catheter incorporates a diplexer for separating and bringing

out from the catheter the two different frequency signals traveling between the catheter and the control unit.

[0013] When the subject catheter is inserted into a patient's blood vessel, the apparatus is able to quickly and accurately measure the blood flow rate in that vessel without the need to introduce foreign substances into that vessel.

### BRIEF DESCRIPTION OF THE DRAWING

[0014] For a fuller understanding of the nature and objects of the invention, reference should be made to the following detailed description taken in connection with accompanying drawing, in which:

FIG. 1 is a diagrammatic view of apparatus for measuring intravascular blood flow in accordance with this invention, and

FIG. 2 is a sectional view of the diplexer component of the FIG. 1 apparatus.

### DESCRIPTION OF THE PREFERRED EMBODIMENT

[0015] Referring to FIG. 1 of the drawing, the present apparatus comprises a flexible catheter shown generally at 10 for insertion into a blood vessel V. Catheter 10 is connected by coaxial cables 12a and 12b to a control unit 14. The catheter has a proximal end 10a to which cables 12a and 12b are connected by way of a fitting or connector 16 and a distal end or tip 10b. In a typical procedure, the catheter may be inserted into the patient through a standard introducer inserted in the patient's neck. The introducer is typically 8.5 French, which the catheter may be 6 or 7 French. The catheter 10 goes from the jugular through the right side of the heart and then into the pulmonary artery.

[0016] As shown in FIG.1, catheter 10 incorporates coaxial inner and outer antennas 22<sub>R</sub> and 22<sub>T</sub>. The inner antenna 22<sub>R</sub> comprises a coaxial cable consisting of an inner conductor 24 and an outer conductor 26 separated by a dielectric layer 28, the outer conductor 26 being surrounded by a thin dielectric sleeve 32. The inner conductor 24 may be formed as a tube to accept a conventional guide wire (not shown) to help guide the catheter 10 into vessel V. The outer antenna 22<sub>T</sub> consists of an inner conductor 34 and an outer conductor 36 separated by a dielectric layer 38. As seen in FIG. 1, the innermost conductor 24 projects beyond the next outer conductor 26 a distance  $L_1$  and constitutes antenna 22<sub>R</sub>. Also, the outermost conductor 36 is set back from the next inner conductor 34 a distance  $L_2$  thus forming the outer antenna 22<sub>T</sub>. The two antennas 22<sub>R</sub> and 22<sub>T</sub> are spaced apart axially a distance D, the conductors in that distance D basically constituting a short transmission line. Preferably, the inner coaxial cable constituting antenna 22<sub>R</sub> is slidable relative to conductor 34 and remaining outer conductors and fitting 16, enabling the adjustment of the distance D between the two antennas 22<sub>R</sub> and 22<sub>T</sub>.

[0017] At fitting 16, the proximal ends of conductors 24, 26, 34 and 36 are connected by way of a passive diplexer 42 (FIG. 2) in fitting 16 to the coaxial cables 12a and 12b. Preferably, the implantable segment of catheter 10 has a protective dielectric outer coating, e.g. of PTFE, (not shown).

[0018] Still referring to FIG. 1, the control unit 14 comprises a microwave transmitter 44 which operates under the control of a processor 46 in unit 44 to deliver microwave pulses at a fixed frequency  $F_T$  via cable 12a to antenna 22<sub>T</sub> in catheter 10. Preferably, transmitter 24 is a solid state programmable transmitter which may operate at, say, 915MHz and may have a maximum power output of 0 to 120 watts. Such a transmitter is

available from Meridian Medical System, Inc. Acton, MA. That transmitted power causes antenna 22<sub>T</sub> to emit electromagnetic radiation which heats the blood in the region L<sub>2</sub> surrounding that antenna.

[0019] The control unit 14 also includes a microwave receiver 46 which receives signals F<sub>R</sub> from antenna 22<sub>R</sub> via cable 12b. Preferably, the radiometer is a Dicke-switch radiometer of the type available from Meridian Medical System, Inc., Ayer, MA. It has a radiometer frequency in the range of 3.7 to 4.2 GHz, with a center frequency of 4.0 GHz. When a temperature anomaly is picked up from the region L<sub>1</sub> surrounding antenna 22<sub>R</sub>, that signal F<sub>R</sub> is detected by receiver 48 which delivers a corresponding output signal to processor 46. The processor thereupon computes the blood flow rate and sends a control signal to a display device 52, e.g. CRT, printer, plotter, etc., in unit 14 which displays that flow rate.

[0020] The pulse rate of the transmitter 44 and the information displayed on display 52 may be controlled by entering appropriate data into the processor via the processor's keyboard 46a.

[0021] Also as noted above, the distance D between the two antennas 22<sub>R</sub> and 22<sub>T</sub> may be varied to optimize the performance of the two antennas, that distance also being entered into the processor 46 via keyboard 46a.

[0022] Refer now to FIG. 2 which shows the diplexer 42 in detail. As seen there, the diplexer includes a quarter-wave ( $\lambda/4$ ) stub to bring out the signal F<sub>R</sub> from the inner antenna 22<sub>R</sub>. The stub also provides a matched 90° bend to separate and bring out the signal

$F_T$  from the outer antenna  $22_T$  so that the signal from the transmitter 44 is not coupled to the receiver 46 and vice versa.

[0023] While it is known in the art to use a quarter-wave stub to support the center conductor of an antenna, the present diplexer has a tubular inner conductor 58 which receives the coaxial cable 24-32 comprising the inner antenna  $22_R$  that provides the signal  $F_R$ .

That conductor 58 may be an extension of the antenna conductor 34. Surrounding and being insulated from conductor 58 is a coaxial outer conductor 62 which may be an extension of antenna conductor 36. The two diplexer conductors 58 and 62 are shorted by an end plate 64. Conductor 58 has a branch 58a which is brought out through a tubular branch 62a of conductor 62 to enable the delivery of the signal  $F_T$  to antenna  $22_T$ . Preferably, the coaxial cable 24-32 is slidable to some extent along conductor 58 to vary the antenna distance  $D$  as described above.

[0024] The illustrated diplexer 42 provides distinct advantages in that it separates the concentric cables from antennas  $22_R$  and  $22_T$  in FIG. 1 into two separate cables and it allows those cables to be mechanically positioned independently.

[0025] When catheter 10 is inserted into a patient's blood vessel  $V$  and the control unit 14 is activated, transmitter 44 applies microwave pulses to antenna  $22_T$ . The microwave energy heats the blood in the volume  $L_2$  around that antenna. That volume then travels to the region  $L_1$  around antenna  $22_R$  which senses the increased thermal energy from that volume and applies a corresponding signal to receiver 48. The processor 46 thereupon computes the elapsed time between the transmitted signal and the received signal and divides that time into the distance  $D$  between the two antennas to produce the measured blood flow rate which may then be displayed by the display device 52. All of this is done



quickly and accurately without the necessity of introducing any foreign substance into the patient's blood stream. Moreover, there are no components in the catheter whose ages may effect their ability to accurately heat and detect the rate of flow of the blood in the vessel V.

[0026] As noted above, the spacing D of the two antennas 22<sub>R</sub> and 22<sub>T</sub> may be adjusted to optimize the performance of the antennas and of the catheter 10 as a whole. As described above, the diplexer 42 accommodates such sliding movement while still separating the signals on the two antennas so that the signal transmitted by antenna 22<sub>T</sub> is not received by the receiver 48 and conversely, the signal received by antenna 22<sub>R</sub> is not coupled to the transmitter 44.

[0027] It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained. Also, certain changes may be made in carrying out the above method and the construction set forth without departing from the scope of the invention. For example, the positions of the two antennas 22<sub>R</sub> and 22<sub>T</sub> may be reversed in which case the diplexer would have a length ( $\lambda_R/4$ ). Therefore, it is intended that all matter contained in the above description or shown in the accompanying drawing shall be interpreted as illustrative and not in a limiting sense.

[0028] It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention described herein.

What is claimed is: